MIDCAREER INVESTIGATOR AWARD IN PATIENT-ORIENTED RESEARCH

Release Date: April 6, 1998

PA NUMBER: PA-98-053

P.T.

National Institute on Aging

National Institute on Alcohol Abuse and Alcoholism

National Institute of Allergy and Infectious Diseases

National Institute of Arthritis and Musculoskeletal and Skin Diseases

National Cancer Institute

National Center for Research Resources

National Institute of Child Health and Human Development

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National Heart, Lung, and Blood Institute

National Institute of Mental Health

National Institute of Neurological Disorders and Stroke

Office of Alternative Medicine

Application Receipt Dates: February 1, June 1, and October 1

THIS PA USES THE "JUST IN TIME" CONCEPT(as described in the NIH GUIDE FOR GRANTS AND CONTRACTS, Volume 25, Number 10, March 29, 1996, and Volume 25, Number 16, May 17, 1996). IT INCLUDES DETAILED MODIFICATIONS TO STANDARD APPLICATION INSTRUCTIONS THAT MUST BE USED WHEN PREPARING APPLICATIONS IN RESPONSE TO THIS PA.

PURPOSE

The purpose of the Midcareer Investigator Award in Patient-Oriented Research (K24) is to provide support for clinicians to allow them protected time to devote to patient-oriented research and to act as mentors for beginning clinical investigators. The target candidates are outstanding clinical scientists engaged in patient-oriented research who are within 15 years of their specialty training, who can demonstrate the need for a period of intensive research focus as a means of enhancing their clinical research careers, and who are committed to mentoring the next generation of clinical investigators focussing on patient-oriented research. The award is intended to further the research and mentoring endeavors of outstanding patient-oriented investigators, enable them to expand their potential to make significant contributions to their field of patient-oriented research, and to act as mentors for beginning clinicians.

For the purposes of this award, patient-oriented research is defined as research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator directly interacts with human subjects. This area of research includes: 1) mechanisms of human disease; 2) therapeutic interventions; 3) clinical trials, and; 4) the development of new technologies.

The NIH is especially interested in increasing the number of scientists trained to conduct high-quality clinical research. Accordingly, this award forms an important part of the NIH initiative to attract and retain talented individuals to the challenges of patient-oriented research. With a view towards stabilizing clinical research settings and preventing an interruption in trainee mentoring, the NIH has chosen to establish the MIDCAREER INVESTIGATOR AWARD IN PATIENT-ORIENTED RESEARCH. This award is intended to relieve clinical investigators from patient care duties and administrative responsibilities, thereby increasing the opportunities for clinicians in midcareer to be well grounded in patient-oriented research. This initiative is consistent with the recommendations of the NIH Director's Panel on Clinical Research (http://www.nih.gov/news/crp/index.html) and the recommendations from the Institute of Medicine Committee on Addressing Career Paths for Clinical Research.

The objectives of the Midcareer Investigator Award in Patient-Oriented Research (K24) are to:

- encourage midcareer clinicians to devote more time to patient-oriented research and enhance their clinical research skills in order to conduct meritorious patient-oriented research and mentor beginning clinical investigators.
- increase the pool of clinical researchers who can conduct patient-oriented studies, capitalizing on the discoveries of biomedical research and translating them to clinical settings.

This Award will enable candidates holding clinical degrees (see ELIGIBILITY REQUIREMENTS below) to undertake up to five years (a minimum of three years is required) of patient-oriented research, thereby further developing their research skills, devoting time to patient-oriented research, and acting as a mentor and role model for beginning clinical researchers.

The prospective candidate for the Midcareer Investigator Award in Patient-Oriented Research should propose a period of patient-oriented research consistent with his/her research and clinical experience and further development of research skills. All programs should be carefully tailored to meet the individual needs of the candidate and must include a description of a research project that meets the definition of patient-oriented research. In addition, the candidate should have a demonstrated record of conducting meritorious patient-oriented research and have experience in mentoring (or demonstrate mentoring capabilities) and describe mentoring activities that will involve beginning clinicians with little or no research experience. The applicant must have independent research support at the time of application for this program. This award is intended to enable the candidate to devote a greater percent effort to patient-oriented research.

HEALTHY PEOPLE 2000

The Public Health Service is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program Announcement, Midcareer Investigator Award in Patient-Oriented Research, is related to the priority area of human resource development. Potential candidates may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) from the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/512-1800) or electronically (http://odphp.osophs.dhhs.gov/pubs/hp2000).

ELIGIBILITY REQUIREMENTS

Candidates for this award must have a clinical degree or its equivalent, including the M.D., D.O., D.D.S., D.M.D., O.D., D.C., N.D. (Doctor of Naturopathy), and doctorally prepared nurses. In addition, individuals holding the Ph.D. degree may apply for the award if they have been certified to perform clinical duties, such as a clinical psychologist, clinical geneticist, etc. Candidates must have completed their specialty training within 15 years of submitting the application, and there is no age limit for candidates. In exceptional circumstances, the period of eligibility may be extended

if it can be demonstrated that candidates had an interruption in their career progression due to family or personal circumstances.

Candidates must be working in a research environment, conducting patient-oriented research, and have independent research support. Candidates must be willing to spend up to 50 percent effort (at least 25%) conducting patient-oriented research and mentoring. All programs should be carefully tailored to meet individual needs and capabilities of candidates.

Applications may be submitted on behalf of candidates by domestic, non-Federal organizations, public or private, such as medical, dental, or nursing schools or other institutions of higher education. Minorities, women and individuals with disabilities are encouraged to apply. At the time of award, candidates must be citizens or noncitizen nationals of the United States, or must have been lawfully admitted to the United States for permanent residence (i.e., in possession of a currently valid Alien Registration Receipt Card I- 551, or other legal verification of such status). Noncitizen nationals are generally persons born in outlying possessions of the United States (i.e., American Samoa and Swains Island). Individuals on temporary visas are not eligible.

A candidate for the MIDCAREER INVESTIGATOR AWARD IN PATIENT-ORIENTED RESEARCH may not concurrently apply for any other PHS award that duplicates the provisions of this award. Recipients of this award are required to hold independent research support, either Federal or private, during the period of this award. However, they may not receive additional compensation on another federal award that exceeds the maximum allowable salary compensation (currently \$125,000 per year.)

MECHANISM OF SUPPORT

Awards in response to this program announcement will use the K24 mechanism. Planning, direction, and, execution of the program will be the responsibility of the candidate on behalf of the applicant institution. The project period may be for up to five years(at least three years are required). Awards are renewable for one additional five year period if the candidate still meets the stated requirements. Specific K24 application instructions have been modified to reflect "JUST IN TIME" streamlining efforts being examined by the NIH. "Just IN TIME" postpones the collection of certain information that currently must be included in all competing applications when submitted. The "JUST IN TIME" concept allows applicants to submit certain information only when there is a possibility for an award. It is anticipated that these changes will reduce the administrative burden for the applicants, applicant institutions, reviewers, and NIH staff.

AWARDS AVAILABLE

The overall goal of the NIH is to support between 60 and 80 awards in Fiscal Year 1999 and in each succeeding year through Fiscal Year 2003. The actual number of awards to be made by each Institute or Center will vary yearly and will be dependent upon the number and quality of applications submitted and funds available.

RESEARCH OBJECTIVES

- A. Environment: The institution must have a well-established research and clinical career development program. The institution must be able to demonstrate a commitment to the candidate as a productive, independent investigator. The candidate and institution must be able to describe a career program that will utilize the relevant research and educational resources and the institution must certify that the candidate will be released from other duties and be able to devote up to 50 percent effort (at least 25 percent effort) to a patient-oriented research program. The Institution must demonstrate the availability of beginning clinical investigators to be mentored.
- B. Program: The award provides up to five consecutive 12-month awards. Up to 50 percent of the investigator's effort (at least 25 percent) must be devoted to the patient-oriented research program and mentoring. The remainder may be devoted to other clinical, teaching, or research pursuits consonant with the objectives of the award. The research phase of an award period must be devoted to patient-oriented research in scientific areas relevant to the career goals of the candidate.

C. Allowable Costs:

1. Salary: The NIH will provide salary for the award recipient of up to \$62,500 per year plus commensurate fringe benefits for up to 50 percent effort. At least 25 percent effort is required. The institution may supplement the NIH contribution up to a level that is consistent with the institution's salary scale. Institutional supplementation of salary must not require extra duties or responsibilities that would interfere with the purpose of the award.

Recipients of this award may derive additional compensation from other Federal sources or awards provided the total salary derived from all Federal sources does not exceed \$125,000 per year and their total percent effort does not exceed 100 percent. Direct salary is exclusive of fringe benefits and facilities and administrative costs.

The total salary requested must be based on a full-time, 12-month staff appointment. It must be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the department concerned. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary structure.

- 2. Research Development Support: The NIH will provide generally up to \$25,000 per year for the following expenses: (a) research expenses, such as supplies, equipment and technical personnel for the principal investigator and his/her mentored clinical investigators; (b) travel to research meetings or training; (c) statistical services including personnel and computer time.
- 3. Ancillary Personnel Support: Salary for secretarial, and administrative assistance etc., is not allowed.
- 4. Facilities and Administrative costs: These costs will be reimbursed at 8 percent of modified total direct costs.
- D. Evaluation: In carrying out its stewardship of human resource related programs, the NIH may request information essential to an assessment of the effectiveness of this program. Accordingly, recipients are hereby notified that they may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.
- E. Special Leave: Leave to another institution, including a foreign laboratory, may be permitted if directly related to the purpose of the award. Only local, institutional approval is required if such leave does not exceed 3 months. For longer periods, prior written approval of the NIH funding component is required. To obtain prior approval, the award recipient must submit a letter to the NIH describing the plan, countersigned by his or her department head and the appropriate institutional official. A copy of a letter or other evidence from the institution where the leave is to be taken must be submitted to assure that satisfactory arrangements have been made. Support from the career award will continue during such leave.

Leave without award support may not exceed 12 months. Such leave requires the prior written approval of the NIH funding component and will be granted only in unusual situations. Support

from other sources is permissible during the period of leave. Such leave does not reduce the total number of months of program support for which an individual is eligible. Parental leave will be granted consistent with the policies of the NIH and the grantee institution.

F. Termination or Change of Institution: When a grantee institution plans to terminate an award, the NIH funding component must be notified in writing at the earliest possible time so that appropriate instructions can be given for termination. If the individual is moving to another eligible institution, career award support may be continued provided:

A new career award application is submitted by the new institution;

All conditions of the award are met at the new institution;

The period of support requested is no more than the time remaining within the existing award period; and

The new application is submitted far enough in advance of the requested effective date to allow the necessary time for review.

The funding component may require a review by an initial review group and/or the appropriate National Advisory Council or Board. Alteratively, review may be carried out by staff within the NIH funding component depending upon the circumstances.

The NIH may discontinue an award upon determination that the purpose or terms of the award are not being fulfilled. In the event an award is terminated, the Director of the NIH shall notify the grantee institution and career award recipient in writing of this determination, the reasons therefor, the effective date, and the right to appeal the decision.

A final progress report, invention statement, and Financial Status Report are required upon either termination of an award or relinquishment of an award in a change of institution situation.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

For research projects involving human subjects, it is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the

health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which has been published in the Federal Register of March 28,1994 (FR 59 14508-14513), and in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18,1994, Volume 23, Number 11. It is also available electronically at http://www.nih.gov/grants/guide/notice-files/not94-100.html

Investigators may obtain copies from these sources or from the program staff or contact person listed below. Program staff may also provide additional relevant information concerning the policy.

NIH POLICY AND GUIDELINES ON THE INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all applications submitted in response to this Program Announcement. All investigators proposing research involving human subjects should read the "NIH POLICY AND GUIDELINES ON THE INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS" that was published in the NIH GUIDE FOR GRANTS AND CONTRACTS, March 6, 1998 and is available at the following URL address: http://www.nih.gov/grants/guide/notice-files/not98-024.html

As part of the scientific and technical merit evaluation of the research plan, reviewers will be instructed to address "the adequacy of plans for including children as appropriate for the scientific goals of the research, or justification for exclusion.

APPLICATION PROCEDURES

This is an NIH-wide program announcement for the Midcareer Investigator Award in Patient-Oriented Research. Therefore, all candidates are strongly encouraged to contact the staff person in the relevant institute or center listed under INQUIRIES. Such contact should occur early in the planning phase of application preparation. Such contact will help ensure that applications are responsive to the goals and policies of the individual institute or center.

Applicants who will be using a General Clinical Research Center (GCRC) are requested to include a letter from either the GCRC program director or the principal investigator with the application.

Applications are to be submitted on the grant application form PHS 398 (rev.5/95-use the instructions in Section IV as appropriate) and will be accepted on or before the receipt dates indicated in the application kit. Forms are available at most institutional offices of sponsored research and from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, Phone (301) 435-0714, FAX: (301) 480-0525, Email: asknih@od.nih.gov. Forms are also available on the NIH Website at http://www.nih.gov/grants/funding/phs398/phs398.html

To identify the application as a response to this program announcement, check "YES" on item 2 of page 1 of the application and enter "PA-98-053, Midcareer Investigator Award in Patient-Oriented Research."

Submit a signed, typewritten original of the application with five signed photocopies, in one package to:

CENTER FOR SCIENTIFIC REVIEW (FORMERLY DIVISION OF RESEARCH GRANTS)
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817-7710 (for express/courier service)

The application must contain the following:

Candidate

- o A description of the candidate's commitment to a career in patient-oriented research.
- o Evidence of the candidate's ability to conduct high quality patient-oriented research.
- o A description of immediate and long-term career objectives, explaining how the award will contribute to their attainment.

o A description of how the award will contribute to a patient-oriented research program and how it will relieve the candidate from other patient care or administrative duties.

Research Plan

- o A commitment of up to 50 percent effort(at least 25 percent effort) to the patient-oriented research program.
- o A description of the ongoing patient-oriented research. The research plan should briefly describe the specific aims, the background and significance of the studies, and the research design and methods. Additional research may be proposed as a basis for this award.
- o Documentation that appropriate and adequate resources, both in terms of support and facilities, are available to the candidate to conduct the research program. This must include a description of other monetary support that will be utilized to conduct the research program.

Mentoring Plan

- o A demonstrated record of mentoring or training clinical investigators or a demonstration of the capability to provide mentoring to beginning clinical investigators.
- o A description of plans for providing mentoring opportunities to beginning clinical investigators, including a description of the type of clinical investigators that could be mentored, plans for recruiting and selecting such individuals, and the type of training and educational experiences to be provided.

Environment and Institutional Commitment

- o The sponsoring institution must document a strong, well-established patient-oriented research and training program related to the candidate's area of interest including a high-quality research environment with staff capable of productive collaboration with the candidate. The sponsoring institution also must provide a statement of commitment to enhancing the candidate's ability as a productive, independent investigator.
- o The sponsoring institution must provide documentation that the candidate will be relieved from other duties, patient care, administrative, etc., to allow him/her to devote time to the patient-oriented research program.

Budget Instructions

The total direct costs must be requested in accordance with the K24 program guidelines, following the budget instructions described below.

- o Face Page-As a reminder, Item 7 should be completed to indicate direct costs requested and Item 8 should reflect total costs(direct plus Facilities and Administrative)
- o Detailed Budget for Initial Budget Period Do not complete form page 4 of the PHS 398 (rev. 5/95). It is not required nor will it be accepted at the time of application. In some cases it may be requested prior to award.
- o Budget for Entire Proposed Period of Support Do not complete the categorical budget table on form page 5 in the PHS 398 (rev. 5/95). Only the requested total direct costs for each year and total direct costs for the entire proposed period of support should be shown.
- o Begin the budget justification in the space provided, using continuation pages as needed.
- o List the name, role on project and percent effort for all project personnel (salaried or unsalaried) and provide a narrative justification for each person based on his/her role on the project and proposed level of effort.
- o Identify all consultants by name and organizational affiliation and describe the services to be performed.
- o Provide a narrative justification for any major budget items, other than personnel, that are requested for the conduct of the project that would be considered unusual for the scope of research. No specific costs for items or categories should be shown.
- o Facilities and Administrative costs will be calculated at the time of the award using the 8% rate. Applicants will be asked to identify the exclusions prior to award.
- o If consortium/contractual costs are requested, provide the percentage of the subcontract total costs (direct plus Facilities and Administrative) relative to the total direct costs of the overall project. The subcontract budget justification should be prepared following the instructions provided above.

Biographical Sketch

A biographical sketch is required for all key personnel, following the modified instructions below. Do not exceed the two-page limit for each person.

- o Complete the education block at the top of the form page.
- o List current position(s) and those previous positions directly relevant to the application.
- List selected peer-reviewed publications directly relevant to the proposed project, with full citation.
- o Provide information on research projects completed and/or research grants participated in during the last five years that are relevant to the proposed project. Title, principal investigator, funding source, and role on project must be provided.

Other Support

Do not complete the other support page (format page 7 of the PHS 398 (rev.5/95)). Information on active support for key personnel will be requested prior to award. A completed checklist will be required prior to award.

REVIEW CONSIDERATIONS

Applications will be reviewed for completeness by the Center for Scientific Review and for responsiveness to this program announcement by the appropriate institute or center staff. Incomplete or non-responsive applications will be returned to the applicant without further consideration. Applications that are complete and responsive to the program announcement will be evaluated for scientific and technical merit by a peer review group convened by the appropriate Institute or Center in accordance with the standard NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate national advisory council or board.

The following review criteria will be applied:

Candidate

- Quality of the candidate's academic and clinical record, including capabilities and commitment to serve as a mentor;
- o Evidence of ongoing high quality patient-oriented research and the relationship of that research to this program;
- o Potential to conduct quality patient-oriented research;
- o Commitment to a patient-oriented research career;
- o Appropriateness of the content and duration of the proposed research program;
- o Evidence of monetary support for patient-oriented research.

Research Plan

Although it is understood that K24 applications do not require the level of detail necessary in regular research grant applications, a fundamentally sound research plan must be provided. In general, less detail is expected with regard to research planned for the later years of the award, but the application should outline the general goals for these years.

- o Appropriateness of the research plan as a vehicle for demonstrating skills and capabilities in patient-oriented research.
- o Scientific and technical merit of the proposed research.
- o Relevance of the proposed research to the candidate's career objectives;
- o Availability of adequate resources to conduct the research program;
- o Demonstration that the proposed program will relieve the candidate from other patient care or administrative duties and allow him/her to devote time to patient-oriented research; and

- o Adequacy of the plan's attention to gender and minority issues associated with projects involving human subjects.
- o Adequacy of plans for including children as appropriate for the scientific goals of the research, or justification for exclusion.

Mentoring Plan

- o Experience and potential to serve as a mentor.
- o Adequacy of the plans for mentoring or supervising beginning clinicians in patient-oriented research.

Environment and Institutional Commitment

- Applicant institution's commitment to the scientific development of the candidate and assurances that the institution intends the candidate to be an integral part of its research program;
- o Adequacy of research facilities and the availability of appropriate educational opportunities;
- o Quality and relevance of the environment for scientific and professional development of the candidate and others pursuing patient-oriented research; and
- o Applicant institution's commitment to provide adequate time for conduct of the research program.

AWARD CRITERIA

The institute or center will notify the applicant of the board or council's action shortly after its meeting. Funding decisions will be made based on the recommendations of the initial review group and council/board, the need for research personnel in specific program areas, and the availability of funds. The NIH policy on submission of revised (amended) applications limits the number of such applications to two.

INQUIRIES

Written and telephone inquiries concerning this program announcement are strongly encouraged especially during the planning phase of the application. Below is a listing of each institute's or center's program contact.

Direct inquiries regarding programmatic issues to:

Mary D. Leveck, Ph.D., R.N.
Scientific Program Administrator
National Institute of Nursing Research
Building 45, Room 3AN-12
Bethesda, MD 20892-6300

Telephone: (301) 594-5963

FAX: (301) 480-8260 Email: mary_leveck@nih.gov

James A. Lipton, DDS, Ph.D.

National Institute of Dental Research Natcher Building, Room 4AN-18J

Bethesda, MD 20892-6402 Telephone: (301) 594-2618 or 594-7710

FAX: (301) 480-8318

Email: liptonj@de45.nidr.nih.gov

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6120 Executive Boulevard, Suite 350

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Rockville, MD 20852 (for express/courier service)

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6705 Rockledge Drive, Room 6120

Bethesda, MD 20892-7965

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Research Triangle Park, NC 27709

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AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.855 and 93.856. Awards are made under the authority of title III, Section 301of the PHS Act as amended. The Code of Federal Regulations, Title 42 Part 52 and Title 45 Part 74, are applicable to this program. This program is not subject to the intergovernmental review requirements of Executive Order 12372 to Health Systems Agency review.

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Return to Volume Index
Return to NIH Guide Main Index